



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P0133PCT	FOR FURTHER ACTION See Form PCT/PEA/416	
International application No. PCT/ES2004/000147	International filing date (day/month/year) 31.03.2004	Priority date (day/month/year) 31.03.2003
International Patent Classification (IPC) or national classification and IPC C12N7/04		
Applicant CONSEJO SUPERIOR DE INVESTIGACIONES CIENT... et al		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand 27.01.2005	Date of completion of this report 13.07.2005	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Scheffzyk-Sonnauer, Telephone No. +49 89 2399-8602 	

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/ES2004/000147

JC20 Rec'd PCT/PTO 30 SEP 2005

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-37 as originally filed

Claims, Numbers

1-38 as originally filed

Drawings, Sheets

1/9-9/9 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-7,9,12,16,18,19,21,23-25,28-30,35-38
	No: Claims	8,10,11,13,14,15,17,20,22,26,27,31-34
Inventive step (IS)	Yes: Claims	
	No: Claims	1-38
Industrial applicability (IA)	Yes: Claims	1-38
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

SECTION V-----

As already mentioned in the application (cf. pp. 4 and 5) hitherto a great number of IBDV VLPs have been described in the prior art (cf. e.g. Lombardo E. et al., 1999, J. Virol. 73, 6973-83 (1), cited in the application). Correspondingly, claims relating to such capsids cannot be considered to be novel; i.e. claims 26, 27, 31, 32, 33, 34 lack novelty. As regards claims 32-34 it is noted that an indication of use is not considered limiting the scope of a product claim, i.e. the claim relates to the product as such.

In addition, the HeLa cells described in (1) (see section Materials and Methods) coinfecting with VT7LacOI/POLY and VT7LacOI/VP1 anticipate at least novelty of claims relating to expression systems wherein the first and second promoter are identical (see e.g. claim 8b, 10, 11, 13, 14, 15, 17). Correspondingly in view of the disclosure of (1) claims 20 and 22 also lack novelty.

Finally, in the light of the teaching of (1) presently claimed subject-matter only can be seen as an obvious alternative to a person skilled in the art working in the field of IBDV. Consequently, for the time being the presence of an inventive step cannot be acknowledged.

SECTION VIII-----

- 1). With respect to claims directed to the use of VLPs as vaccine Applicant's attention is drawn to page 5, lines 4 and 5 of present application where it is stated that the capsids taught in (1)- which are identical to those as presently claimed- are not suitable for vaccination purposes. This seems to be in contradiction with presently claimed subject-matter, in particular with respect to claims 28-34. Thus, as regards these claims objections under Art. 6/5 PCT also arise.
- 2). Claims containing the term "corresponding to" are objected to under Art. 6 PCT for lack of clarity since said term does not convey an exact meaning.

SECTION VII-----

**INTERNATIONAL PRELIMINARY
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(SEPARATE SHEET)**

International application No.

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- 1). According to claims 8b, 10 and 25 the first and second promoter must not be different as required in claim 1 but can be the same. This option possibly entails problems inter alia with respect to unity.
- 2). In its broadest meaning the term "expression system" covers human beings which are per se not patentable.
- 3). Claims 21 and 22 seem to be redundant in view of claim 20.